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09/543,268	04/05/2000	Todd M. Boyce	285-79 CON	6472

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EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/15/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/543,268

Applicant(s)

BOYCE ET AL.

Examiner

Paul B. Prebilio

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-21, 23-43, 45-61, 63-80 and 82-144 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-21, 23-43, 45-61, 63-80 and 82-144 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Specification***

The disclosure is objected to because of the following informalities:

On page 1 of the specification, the continuing data does not include the filing date of the parent application; and thus, it is considered incomplete.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 13, 14, 19-21, 23, **24**, 34-43, 45, 56-61, 63, 74-80, 82, 93-94, and 135-140 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyle (US 5,061,286), or alternatively, under 35 U.S.C. 103(a) as being anticipated by Lyle et al (US 5,061,286) alone. Lyle anticipates the wherein demineralized bone particles have had there minerals removed such that the surfaces thereof are collagen. In addition, the particles are linked together with the binder such as cyanoacrylate; see especially column 2, lines 63-68 and column 4, lines 12-20.

The Examiner posits that the adhesives or binders inherently act via covalent or non-covalent bonds. Even if the adhesives or binders were said to not act through covalent bonds, since adhesives and binders of Lyle can act via hydrogen bonding, Van der Waals bonds, ionic bonds, and other non-covalent bonds, the Examiner posits that the present claims are inherently met in this regard.

Alternatively, one may not consider the process of making limitations met because Lyle does not specifically set forth that the bonding is by chemical means or that the certain treatments used to form the bonds are performed as set forth by the present claims. However, the Examiner posits that the same or substantially the same product is formed in Lyle as that claimed in the presently claimed invention; see MPEP 2113, which is incorporated herein by reference. For this reason, the claimed inventions are considered at least clearly obvious over Lyle alone.

With regard to claim 6 specifically, the figures show a ring shaped cross-section around the hip implant stem.

With regard to claims 1-7, 9-10, 23, 45, 63, and 82, the material of Lyle is a solid material so it inherently has a tensile strength even though one is not disclosed. Since the Office does not have testing facilities to determine the tensile strength thereof, the Examiner hereby asserts that the tensile strength of Lyle is inherently within the claimed range.

With regard to claims 13, 14, **24**, 36, 40, 58, and 76, the limitations set forth in these claims are process limitations even though the claims are drawn to a product. For this reason, the Examiner asserts that the claimed product is fully met by Lyle even

though a different method was used to make it because bonds with the collagen and binding agent are present; see MPEP 2113 which is incorporated herein by reference thereto.

Claims 1-7, 9-21, 23-43, 45-61, 63-80, and 82-144 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyce et al (US 5,899,939); see the entire document which is virtually identical to the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle (US 5,061,286) alone. Lyle discloses the use of a binding agent in general and of a crosslinking molecule of cyanoacrylate specifically but does not disclose the use of the particular crosslinking agents as claimed. However, the Examiner posits that it would have been obvious to use another crosslinking agent in view of the broad teaching of Lyle for a binding agent absent some showing that the particular agent had some unexpected/unobvious result.

***Response to Arguments***

Applicant's arguments filed October 1, 2003 have been fully considered but they are not persuasive.

In traversing the rejection, Applicant states that cyanoacrylate adhesives do not form chemical bonds with the collagen. The Examiner disagrees. To support his position, the Examiner has cited a patent to Huo et al (US 6,464,999) that explicitly states that cyanoacrylate adhesives covalently bond to tissue surfaces; see column 25, lines 51-65. Since the claimed invention is made with tissue that contains collagen and since the tissue discussed in Huo are collagen-containing tissues, it follows that the cyanoacrylate adhesives covalently bond to the tissue elements of Lyle.

The prior art citations are noted. However, since they are directed to adhesives in general and not nearly as closely related to the art as Huo, it is the Examiner's position that Huo is more relevant here.

With regard to the traversal of the Boyce rejection, the Examiner notes that Applicant relies on the 37 CFR 1.131 declaration to show patentability. However, the declaration filed on October 1, 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Boyce et al (US 5,899,939) reference.

(1). There is a failure to show due diligence from the period of January 9 to January 28, 1998. In particular, the period of inactivity from January 9 until January 28, 1998, especially January 19 until January 28, where comments from the reviewers should have been back to Dr. Boyce, is not explained. It is noted that even a 2 day delay has been considered fatal where the delay was not explained; see MPEP 2138.06. However, the present delay of 9 days (from January 19 to January 28) is considerably longer. Since there is no comment in the declaration as to what occurred in those 9 days, the Examiner asserts that the declaration is insufficient.

(2). The declaration does not compare all the claims to the evidence provided. In particular, the Examiner notes that only claim 1 was compared to the evidence provided. However, the additional 143 claims with 9 other independent claims have not been compared to the draft specification of the declaration; see MPEP 715.02. For this reason, the Examiner asserts that the declaration fails to provide an adequate comparison between the claimed invention and the evidence as required. In order to overcome this deficiency, the Examiner suggests reducing the number of claims to a reasonable number, such as 20 claims with 3 independents, and then making a similar comparison as that done for claim 1 in the October 1, 2003 declaration.

### ***Conclusion***


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

  
**Paul B. Prebilic**  
Primary Examiner